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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,845

10/29/2003

Steven Savage

1105-003US02

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

12/02/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/695,845	Applicant(s) SAVAGE ET AL.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19,36,37 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19,36,37 and 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/15/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to applicant's communication of 10/10/2008. Currently amended claims 17-19, 36-37, and 39-46 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 10/10/2008 have been fully considered but they are not persuasive. Applicant's argue that the prior art fails to show forces that are "substantially balanced in both axial and radial directions" as in the newly amended claims.

Examiner is of the position that this is taught and shown in the prior art. Examiner draws applicant's attention to figures 14 and 16 of Sandimore (showing a balanced configuration) for embodiments which satisfy and disclose the claimed limitation. Also applicant's attention is drawn to column 8 line 51 through column 9 lines 16). What is disclosed is the teaching of having outlets equal around the catheter or also varying the outlets so as to steer the catheter. It is examiners position that the device is balanced both in axial and radial directions, and there is also a teach to vary the openings to provide movement. Since the device is balanced and equal then the forces resulting from fluid flow would be "**substantially net fluid force of zero**".

Again, applicant is reminded that during examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Under these guidelines examiner is giving a broad reading to the

term “substantially balanced”. Examiner is reading “substantially balanced to mean “being in harmonious or proper arrangement or adjustment, proportion, etc”,

If applicant has a different “balance” of forces or a specific definition of the term balance which they wish to incorporate applicant is recommended to amend the claims to include this.

The elements disclosed in the prior art of record are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19, 36-37, and 39-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sandmore et al. (U.S. Patent Number 6,059,760).

Sandmore discloses a cannula (catheter) having a reverse flow tip (see figures 1-3 and 12-19). Sandmore discloses a catheter for use in a medical procedure, with an elongate tubular structure (36, 46, 38, 45, 28) (fully capable of meeting the size, flow rate), elastic restrictor, and plurality of stem section hole openings formed on the side walls (see elements 100 of figures 12-19) angled toward the proximal end of the catheter for a retrograde fluid stream.

It is examiners position that it is inherent and/or implicit in Sandmore that the tubular structure on the tip section has elastic restrictors that are fully capable and would change size in response to a change in fluid flow (increase in fluid flow) which would provide a variable amount of fluid force restriction. It is examiners position that the tubular structure on the tip section (as in figure 13) contains openings (100 and/or 132) which are made of an elastic material and whose shape would increase if a large volume or high velocity of fluid were to flow out of these openings. These openings, because of the material of which they are made from, and the structure and orientations of them would be fully capable of satisfying the claimed limitations of the elastic restrictor. Similar to how a hole in a water balloon would increase if squeezed or water pressure increased (water balloon with hole attached to a faucet). The fact that the structure exists and is made of an elastic material would be evidence of this structure and capacity to perform this function. It is examiners position that the openings would

be fully capable of all structural, functional, operational and spatial limitations as currently amended in the claims.

In the alternative if not inherent or obvious from Sandmore alone, Claims 17-19, 36-37, and 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandmore in view of Jones et al. (U.S. Patent Number 5,843,050).

Sandmore discloses a cannula (catheter) having a reverse flow tip (see figures 1-3 and 12-19). Sandmore discloses a catheter for use in a medical procedure, with an elongate tubular structure (36, 46, 38, 45, 28) (fully capable of meeting the size, flow rate), elastic restrictor, and plurality of stem section hole openings formed on the side walls (see elements 100 of figures 12-19) angled toward the proximal end of the catheter for a retrograde fluid stream.

If the openings of Sandmore (as disclosed above) do not satisfy the claim limitations requiring an “elastic restrictor” it would be an obvious modification to have an elastic restrictor on the Sandmore tubular structure. Sandmore discloses the claimed invention except for the elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction. Jones teaches that it is known to use an elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction (as set forth beginning with paragraphs at column 11 line 14 through 63 for example and shown in figures 5 and 7) to provide a way to control fluid flow through the catheter by minimizing

fluid flow in the opposite direction or permit the escape of pressurized fluid media. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Sandmore with an elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction as taught by Jones, since such a modification would provide the catheter with an elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction for providing a way to control fluid flow through the catheter by minimizing fluid flow in the opposite direction or permit the escape of pressurized fluid media.

Further, concerning the other claim limitations, Sandmore discloses a hub section (42), a shaft section (36), and a stem section (22), and distal tip with a small opening comprising an elastic restrictor (138,100) and is fully capable, or in the alternative an obvious configuration to one of ordinary skill in the art, of providing a variable amount of fluid force restriction based upon a fluid flow rate through said catheter assembly, such that the forces resulting from the flow is substantially balanced or substantially zero fluid force in all directions (see paragraphs at column 8 through 9). Sandmore discloses that the distal end of the catheter is made of a material that is softer than a material of the proximal end (see paragraphs beginning at column 3). Further the Sandmore tubular structure is fully capable of enabling fluid flow rates in a range of approximately 0 to 40 ml/sec without failure of said tubular structure.

Concerning the size requirements of a device with no greater or about 4 French, diameter approximately 0.305 mm or 0.33 mm, and length of 1.22 mm (claims 17,19-

20,42). Sandmore (or in the alternative Sandmore in view of Jones) discloses the claimed invention except for explicitly teaching the exact size parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a device with no greater or about 4 French, diameter approximately 0.305 mm or 0.33 mm, or a length of 1.22 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

It is examiners position that the size requirements, flow rate requirements, and balanced fluid forces are taught by Sandmore (or in the alternative Sandmore in view of Jones), but in the alternative it would have been an obvious modification to one having ordinary skill in the art at the time the invention was made, to have the specific size requirements (see discussion below), flow rate of approximately 0 to 40 ml/sec, and the balanced/zero fluid force function with the elastic restrictor and catheter assembly.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767